

Message

From: Miller, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FA0582F5BA6540C687844F9289A4F74F-DAVID J. MILLER]
Sent: 10/25/2019 4:12:55 PM
To: Niman, Aaron [niman.aaron@epa.gov]
Subject: RE: Willing to have an informal chat on upcoming AHS activities etc. for FY 2020?

Yes. That's in there. I will specifically mention that.

From: Niman, Aaron <niman.aaron@epa.gov>
Sent: Thursday, October 24, 2019 10:33 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: Willing to have an informal chat on upcoming AHS activities etc. for FY 2020?

Ex. 5 Deliberative Process (DP)

From: Miller, David <Miller.DavidJ@epa.gov>
Sent: Thursday, October 24, 2019 10:29 PM
To: Niman, Aaron <niman.aaron@epa.gov>
Subject: FW: Willing to have an informal chat on upcoming AHS activities etc. for FY 2020?

Thoughts back?

From: Miller, David
Sent: Thursday, October 24, 2019 10:18 PM
To: Thomas, Kent <thomas.kent@epa.gov>
Subject: RE: Willing to have an informal chat on upcoming AHS activities etc. for FY 2020?

Hello Kent,

I'd hope to have these topics jotted down as kind of cheat-sheet for our conversation tomorrow and sent to you further in advance. But please see attached Word document as something we can perhaps use to structure the conversation some. If we aren't able to hit everything in the allotted time, that's ok and maybe we can return to this and add some new ones at a future date.

Do you want to call me (703 305 5352) or should I call you?

I look forward to our conversation.

Regards,

David.

From: Miller, David
Sent: Tuesday, October 22, 2019 1:58 PM
To: Thomas, Kent <thomas.kent@epa.gov>
Subject: RE: Willing to have an informal chat on upcoming AHS activities etc. for FY 2020?

Ex. 5 Deliberative Process (DP)

David.

Ex. 5 Deliberative Process (DP)

From: Thomas, Kent <thomas.kent@epa.gov>
Sent: Tuesday, October 22, 2019 1:35 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: Willing to have an informal chat on upcoming AHS activities etc. for FY 2020?

Thanks, David. I continue to look through information you have provided. One quick question, am I understanding the Tiers correctly for your epi reports:

Ex. 5 Deliberative Process (DP)

Kent

From: Miller, David <Miller.DavidJ@epa.gov>
Sent: Tuesday, October 22, 2019 12:56 PM
To: Thomas, Kent <thomas.kent@epa.gov>
Subject: FW: Willing to have an informal chat on upcoming AHS activities etc. for FY 2020?

Hello Kent,

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https://www.stata.com/meeting/nordic-and-baltic19/slides/nordic19_miller.pdf

and the Stata and SAS code along with a Working Paper with additional details on this topic available here:

<http://www.imm.ki.se/biostatistics/emagnification/>

Short story is that when we see a statistically significant effect size (such as an OR or RR) that might cause us concern but seems to have a low sample size and thus results in which we might have less confidence, we have the ability to use the above code to determine the extent to which the results might be reasonably discounted due to small sample size/low power. Again, no magic answers -- but it does allow us to characterize things better than just a simple and not particularly useful: "it's a statistically significant and moderately strong OR, but sample size is small and there are not

many exposed cases". Anyway, it has introduced a little more rigor into our process that is helpful from a regulatory/decision-making perspective and is one of the reasons the above lettered items are marked in green.

Regards,

David.

From: Miller, David

Sent: Tuesday, October 22, 2019 9:03 AM

To: Thomas, Kent <thomas.kent@epa.gov>

Subject: RE: Willing to have an informal chat on upcoming AHS activities etc. for FY 2020?

Hello Kent,

Another thing that I thought would be useful to share with you is what I've pasted below: the epi/incident documents that the branch has gotten out on incidents and epi over the last FY, with the ones that included epi (because there was at least AHS available) marked below in bold. This will give you an idea of the scope of things we do and - more specifically- the epi we do not do because they are not included in AHS (I am checking on this latter part).

Tier I Updates Finalized:

1. **Phostebupirim: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment**
2. Flumethrin: Tier I Update Review of Human Incidents and Epidemiology for Proposed Interim Decision
3. **Metolachlor and S-Metolachlor: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment**
4. Pyridalyl: Tier I (Scoping) Review of Human Incidents and Epidemiology
5. p-dichlorobenzene (PDCB): Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
6. Triallate: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
7. Boscalid: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
8. **Saflufenacil: Revised Tier I (Scoping) Review of Human Incidents and Epidemiology**
9. **Pyrimethanil: Revised Tier I (Scoping) Review of Human Incidents and Epidemiology**
10. Iprodione: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
11. **Mesotrione: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment**
12. **Spirotetramat: Tier I (Scoping) Review of Human Incidents and Epidemiology**
13. Spiromesifen: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
14. Acequinocyl: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
15. Propargite: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
16. Terbacil: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
17. Pyroxsulam: Tier I (Scoping) Review of Human Incidents and Epidemiology
18. Thien carbazon-methyl: Tier I (Scoping) Review of Human Incidents and Epidemiology
19. 2-Phenylphenol and Salts: Tier I Review of Human Incidents and Epidemiology for Draft Risk Assessment
20. **Mandipropamid: Tier I (Scoping) Review of Human Incidents and Epidemiology**
21. **Triclopyr, salts and esters: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment**
22. **Aluminum Phosphide, Magnesium Phosphide, and Phosphine: Tier I Updated Review of Human Incidents and Epidemiology for Draft Risk Assessment**
23. Fenpyroximate: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
24. Myclobutanil: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
25. **Mecoprop (MCP): Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment**
26. Flonicamid: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
27. Carboxin and Oxycarboxin: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
28. Etoxazole: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
29. Cyproconazole: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
30. Ethoxyquin: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
31. Uniconazole-P: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
32. **Fluazifop-p-butyl: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment**

33. Dikegulac sodium: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
34. Pinoxaden: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
35. Etridiazole: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
36. Fenamidone: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
37. Propanil: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
38. Propylene Oxide (PPO): Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
39. Pyraflufen-Ethyl: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
40. Cyazofamid: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 41. Isoxaflutole: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment**
42. Zoxamide: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
43. Oxyfluorfen: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
44. Fenbutatin Oxide: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
45. Thiabendazole and Salts: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
46. MCPB and Salts: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
47. Aliphatic Solvents: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 48. Pyraclostrobin: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment**
49. Dimethyl Disulfide (DMDS): Tier I Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 50. Methyl Bromide: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment**
51. Naphthalene: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment
- 52. Flumioxazin: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment**
- 53. Clopyralid: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment**
54. 2,4-DP-p (dichloroprop-p): Revised Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment

And recall of course the paraquat epi and the pyrethroids epi links I sent you earlier. We are checking the docket so I can provide links to you and other AHS folks to the above documents so that going in and seeing what we said would be easier: I am thinking that for the upcoming year it might be good for my branch to make a more concerted effort to let AHS folks know a bit more about what we do with epi in general and AHS in particular if you think there is interest on their part.

With respect to more major items we've done in past years – with links to the docket – here are some of them (with the ones in italics being the more recent ones):

Links to Tier I Epi/incident reviews available in the chemical dockets:

- ♣ *Captan*: <https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0296-0045>
- ♣ Trifluralin: <https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0417-0022>
- ♣ *Bromoxynil*: <https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0896-0023>
- ♣ *Imazethapyr*: <https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0774-0022>
- ♣ Carbaryl <https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0230-0035>
- ♣ EPTC <https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0720-0017>
- ♣ Aldicarb <https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0161-0024>

Links to Tier II Epi/incident reviews available in the chemical dockets:

- ♣ *Atrazine*: <https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-1156>
- ♣ *Diazinon*: <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0091>
- ♣ *Permethrin*: <https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0039-0084>
- ♣ *2,4-D*: <https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0330-0084> for carcinogenic effects and <https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0330-0087> for non-carcinogenic effects.

Again, we will work on assembling the above in a more user-friendly format, but I think it would be a good thing for my branch to try to do a bit more communication with AHS researchers than we typically have in the past, if you think that

the AHS folks would welcome it and find it useful. I think we have built up enough of a set of completed documents and experiences to be able to have some productive communications.

Regards,

From: Miller, David

Sent: Monday, October 21, 2019 4:10 PM

To: Thomas, Kent <thomas.kent@epa.gov>

Subject: RE: Willing to have an informal chat on upcoming AHS activities etc. for FY 2020?

You're welcome. And before that I will draw up a list of topic/agenda to provide you ahead of time.

Ex. 5 Deliberative Process (DP)

David.

From: Thomas, Kent <thomas.kent@epa.gov>

Sent: Monday, October 21, 2019 3:58 PM

To: Miller, David <Miller.DavidJ@epa.gov>

Subject: RE: Willing to have an informal chat on upcoming AHS activities etc. for FY 2020?

Thanks, David. Friday will be good for me. I'll review again the 'epi-thoughts' information in advance of our discussion – thanks for your efforts to color-code based on current knowledge/conditions.

Best wishes,
Kent

From: Miller, David <Miller.DavidJ@epa.gov>

Sent: Sunday, October 20, 2019 6:44 PM

To: Thomas, Kent <thomas.kent@epa.gov>

Subject: FW: Willing to have an informal chat on upcoming AHS activities etc. for FY 2020?

Hello Kent,

Does Friday at 10 am work for you? I will do an MS Outlook invite. Feel free to propose an alternative if you want.

Also, I had sent you before (several times over the years, if I recall) my email from 2014 entitled "email_epi thoughts" . I have resent this again now with color notations added to give you a sense of where I feel we are on this. Green highlight means that we have more or less covered that in the ensuing 5 years and I feel we have thought about it pretty deeply are reasonably settled and comfortable on the issue. Yellow means we are still interested in it and beginning to think about it and it might be considered "on deck". No color suggests we really haven't considered it too much yet and would not have too much to say at this time. Note that this all concerns overall regulatory epidemiology, and are not all necessarily specific to AHS. I'd be interested in hearing at some point if you have any thoughts back on these.

On the earlier email (09 June 2014) in the attached that related to an anticipated visit by Dr. Alavanja to OPP (which I think got cancelled and never got rescheduled) , I did raise some specific AHS questions. I think many of those questions are still pertinent and of interest to us.

Regards,

David.

From: Miller, David
Sent: Thursday, October 17, 2019 2:24 PM
To: Thomas, Kent <thomas.kent@epa.gov>
Subject: RE: Pesticide Program Update: EPA Makes Paraquat Draft Risk Assessments Available for Public Comment

Hello Kent,

Moving the date is fine. Let me get back to you in a bit with what's free and offer suggestions. Regardless, I will consider the Monday 21 October date as now being off.

David.

From: Thomas, Kent <thomas.kent@epa.gov>
Sent: Thursday, October 17, 2019 1:49 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: Pesticide Program Update: EPA Makes Paraquat Draft Risk Assessments Available for Public Comment

Hi David:

Thanks very much for the information you have sent me across several emails. It has been interesting to read the Epi Tier II reports for several chemicals. It is clear that you and your group have been putting a lot of effort into these assessments.

Our discussion is tentatively scheduled for Monday October 21st. Would it be OK with you if we moved that back by a couple of days? How does Wednesday October 23rd look for you (my calendar is open all day). Tuesday (10/22) afternoon from 2:30 – 4:00 are also open, as is all day Friday (10/25).

Best,
Kent

From: Miller, David <Miller.DavidJ@epa.gov>
Sent: Wednesday, October 16, 2019 9:17 AM
To: Thomas, Kent <thomas.kent@epa.gov>
Subject: FW: Pesticide Program Update: EPA Makes Paraquat Draft Risk Assessments Available for Public Comment

Hello Kent,

You might also be interested in this for one of our discussion topics. We released our risk assessment for paraquat (Pq) yesterday, including our Epi Tier II review. The PR release is in the email below and we say that

"Historically, EPA has received feedback from the public linking the proper use of paraquat to Parkinson's Disease, however, EPA's review of the available information in the draft assessment did not support a causal relationship."

The link to the Epi Tier II Review in the docket is here:

<https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0855-0124>

I've also attached FYI a Bloomberg News that came out on this earlier yesterday.

David.

Ex. 5 Deliberative Process (DP)

From: Evans, Elizabeth <Evans.Elizabeth@epa.gov>

Sent: Tuesday, October 15, 2019 1:47 PM

To: OPP HED TEB <OPP_HED_TEB@epa.gov>; OPP HED CEB <OPP_HED_CEB@epa.gov>

Subject: FW: Pesticide Program Update: EPA Makes Paraquat Draft Risk Assessments Available for Public Comment

Hi CEB and TEB – the paraquat DRAs are now posted in the docket along with Tier II epi report et al- I checked. They are in the docket. Congratulations.

From: EPA Pesticides Programs <oppt.epa@public.govdelivery.com>

Sent: Tuesday, October 15, 2019 1:26 PM

To: Evans, Elizabeth <Evans.Elizabeth@epa.gov>

Subject: Pesticide Program Update: EPA Makes Paraquat Draft Risk Assessments Available for Public Comment

EPA Makes Paraquat Draft Risk Assessments Available for Public Comment

Today, EPA is taking an important step in its regulatory review of paraquat—an herbicide used in agricultural and commercial settings only. The draft risk assessments are the product of an extensive evaluation of available data on the health and environmental impacts associated with the pesticide. The agency is seeking public input on draft human health and ecological risk assessments. These draft risk assessments are the next step in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registration review process and are not a denial or an approval of the herbicide. Public comments will be accepted until December 16, 2019.

Additional Background

Paraquat is already applied annually to control invasive weeds and plants in more than 100 crops—including cotton, corn, and soybeans, and there are presently no direct alternatives to this product. All paraquat products are Restricted Use Products. Additionally, paraquat products can only be applied by certified pesticide applicators. EPA does not allow the use of paraquat in residential areas.

EPA has taken proactive steps, outside of the standard registration review process, to ensure paraquat is used in a manner that is safe and consistent with the label directions. This includes a safety awareness campaign and changes to labels and product packaging to stop improper uses, which have led to poisonings and deaths. Additionally, specialized training for certified applicators who use paraquat was released earlier this year to ensure that the pesticide is used correctly. EPA is continuing to evaluate the effectiveness of these measures as the agency works to complete the required registration review process.

EPA found no dietary risks of concern when paraquat is used according to label instructions. The draft human health risk assessment identifies potential risks to workers who apply paraquat or enter treated fields after application. There are also potential risks from spray drift to bystanders at the edge of the field. The draft ecological risk assessment identifies potential risks to mammals, birds, adult honey bees, terrestrial plants, and algae. Historically, EPA has received feedback from the public linking the proper use of paraquat to Parkinson's Disease, however, EPA's review of the available information in the draft assessment did not support a causal relationship. As with all aspects of the draft risk assessments, the agency is seeking additional feedback from the public during the 60-day public comment period on the relationship between paraquat and Parkinson's Disease.

After public comments on the human health and ecological risk assessments are reviewed, EPA will determine whether updates or revisions to the assessments are necessary. EPA will propose additional risk mitigation measures, if necessary, in 2020, via its Registration Review Proposed Interim Decision. Learn more about paraquat.

EPA distributes its OPP Updates to external stakeholders and citizens who have expressed an interest in the Agency's pesticide program activities and decisions. This update service is part of EPA's continuing effort to improve public access to federal pesticide information.

For general questions about pesticides and pesticide poisoning prevention, contact the National Pesticide Information Center (NPIC) by email at npic@ace.orst.edu or by visiting the NPIC website.

For information about ongoing activities in the Office of Pesticide Programs, visit our homepage.



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